Supreme Court, U.S.
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No. 97-1831

IN THE
Supreme Court of the United States
OCTOBER TERM, 1997

TEMPIE FORTSON WORTHY,
Petitioner,

v.

COLLAGEN CORPORATION,
Respondent.

On Petition for a Writ of Certiorari to the Supreme Court of Texas

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MEMORANDUM IN OPPOSITION

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QUESTION PRESENTED

Whether 21 U.S.C. § 360k(a) preempts a state statutory claim challenging the safety of a medical device that the Food and Drug Administration has found to be safe and effective and has approved for marketing pursuant to the pre-market approval process under 21 U.S.C. § 360e(c).*

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* Respondent Collagen Corporation has no parent company and no non-wholly owned subsidiaries.

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MEMORANDUM IN OPPOSITION

STATEMENT OF THE CASE

1. Company history and regulatory background.

In the early 1970s, a group of biochemists and physicians at Stanford University developed a purified form of bovine collagen, a natural protein that provides structural support for skin, muscles, tendons, and bones. Together with other investors, they organized petitioner Collagen Corporation ("Collagen") to manufacture and distribute collagen products to be used in various medical treatments. The product at issue in this case, Zyderm® Collagen Implant ("Zyderm"), is injected under the skin to correct or improve soft tissue deficiencies that arise from disease, trauma, or aging.

Zyderm is classified by the Food and Drug Administration ("FDA") as a Class III medical device subject to regulation under the Medical Device Amendments of 1976

("MDA"), 21 U.S.C. §§ 360c-360*l*. With two exceptions not germane to Zyderm, a new Class III medical device may not be introduced to the market until the FDA has determined that it satisfies stringent requirements relating to safety and effectiveness. The proces by which the FDA makes this determination, "known as the 'premarket approval,' or 'PMA' process, is a rigorous one. Manufacturers must submit detailed information regarding the safety and efficacy of their devices, which the FDA then reviews, spending an average of 1,200 hours on each submission." *Medtronic, Inc. v. Lohr,* 116 S.Ct. 2240, 2246-47 (1996). Pursuant to this PMA process, the FDA closely studies the ingredients, components, manufacturing methods, and labeling to be used in conjunction with the device. See 21 U.S.C. § 360e(c), (d); 21 C.F.R. Part 814.

The FDA's approval of a device for marketing pursuant to the PMA process "constitutes approval of the product's design, testing, intended use, manufacturing methods, performance standards, and labeling. The FDA's determination is specific to the product." *Mitchell v. Collagen Corp.,* 126 F.3d 902, 913 (7th Cir. 1997), *cert. denied,* 118 S. Ct. 1300 (1998). In addition, "the PMA process imposes requirements that directly affect[] the safety and effectiveness of the product." *Id.* at 911. Once the device has been approved for marketing, the manufacturer is required by the FDA to adhere to all of the standards established during the PMA process concerning how the device is to be "manufactured, packaged, stored, labeled, distributed, or advertised." 21 C.F.R. § 814.80.

Collagen invoked this rigorous PMA process by filing an application with the FDA for premarket approval of Zyderm in May, 1980:

> The initial application consisted of eight volumes containing safety and effectiveness data, in vitro data, animal data, clinical data from tests with more than five thousand patients, a statement of ingredients, a reference to performance standards, labeling, a biblio-

> graphy, significant articles, manufacturing methods, product samples, and patient report forms. . . . In July 1981 the FDA approved Zyderm subject to several conditions. The FDA restricted Zyderm to prescription use and required that it be distributed with FDA-approved labeling and with a patient manual. . . . Finally, the FDA required Collagen to submit a supplemental PMA before making any changes "that may affect the safety or effectiveness" of Zyderm, including changes in use; labeling; manufacturing facilities, methods, or quality control procedures; subcontractors, suppliers, or distributors; sterilization procedures; packaging; and performance or design specifications, components, or ingredients.

Pet. App. 6a-7a. "Announcing the order granting approval, the FDA stated that Zyderm 'had been shown to be safe and effective.' 46 Fed. Reg. 46394 (1981). Ten years later the FDA again reviewed the product and again found it to be safe." Pet. App. 36a.

2. Facts and proceedings in this case.

a. In 1991 petitioner was injected with Zyderm as treatment for facial wrinkles. Pet. App. 45a. Alleging that the treatment had resulted in serious injury, in 1992 petitioner filed suit against both Collagen and her physician in state court, asserting numerous common-law causes of action. Pet. App. 8a-9a. The trial court granted summary judgment for Collagen on the ground that these tort claims were preempted by 21 U.S.C. § 360k(a), the MDA preemption statute. *Id.* at 9a. That statute bars the states from imposing, with respect to a medical device, "any requirement—(1) which is different from, or in addition to, any requirement applicable under [the MDA] to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under [the MDA]."

Petitioner then dismissed her physician from the case and filed an amended complaint against Collagen, asserting only a statutory cause of action under the Texas

Deceptive Trade Practices Act ("DTPA"). Pet. App. 9a. "The court again granted summary judgment for Collagen on preemption grounds, and Worthy appealed. The court of appeals held that Worthy's DTPA action was preempted and that she had failed to preserve for appeal any complaint concerning her other claims." *Id.*

b. The Texas Supreme Court affirmed. The court first determined, agreeing with the court of appeals, that petitioner had failed to preserve her common-law causes of action. Pet. App. 9a-12a. Accordingly, the court limited "its consideration to Worthy's DTPA claims." *Id.* at 12a. As a matter of Texas law, petitioner's DTPA claims reduced to the assertion that "Zyderm was not safe for her use. She does not contend that Zyderm was manufactured, marketed, or injected in her in any way other than that approved by the FDA. To prevail, therefore, Worthy must prove that Zyderm as approved by the FDA is not safe." *Id.* at 37a-38a. This cause of action, the court held, is squarely preempted by the MDA. *Id.* at 38a.

After giving full and careful consideration to this Court's decision in *Medtronic,* Pet. App. 12a-27a, and upon review of numerous post-*Medtronic* judicial decisions and regulatory developments, *id.* at 27a-36a, the Court concluded that "the details of the FDA's premarketing approval of Zyderm—as opposed to the PMA process in general—are sufficiently specific to have preemptive effect." *Id.* at 36a. The court explained:

> Given the specificity of Collagen's presentation to the FDA, the specificity of the FDA's conditions in granting approval, the amount of time required to obtain approval, the recurrence of the investigation a decade later, the prohibition against deviation from the conditions of approval, and the specific finding by the FDA that Zyderm was "safe and effective," we conclude that the FDA's requirements concerning Zyderm are entitled to preemptive effect under the MDA as construed and applied in *Medtronic.*

Id. at 36a-37a. The court determined that petitioner's state law claim, *i.e.*, that Zyderm is not safe even when produced, sold, and administered in accordance with the FDA's specific requirements, "contradicts not only the FDA's specific finding to the contrary but also the manufacturing, distribution, and labeling protocols approved by the FDA." *Id.* at 38a.

In addition, the court noted that petitioner's claims " 'stand[] as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.' " Pet. App. 38a, quoting *Medtronic,* 116 S.Ct. at 2261 (Breyer, J., concurring). Congress intended for the FDA to provide a definitive "federal determination whether a device is safe." *Id.* Because peititoner's cause of action would displace that federal determination with a competing state determination of safety and effectiveness (a determination made not by a panel of experts but, instead, by a jury of laymen), the court observed that "[i]f an action like Worthy's is not preempted, then we are unsure what kind of action would ever be preempted." *Id.*

ARGUMENT

1. The question of MDA preemption presented in this case is the same as that recently presented to the Court in *Mitchell v. Collagen Corp.*, 126 F.3d 902 (7th Cir. 1997), *cert. denied,* 118 S. Ct. 1300 (1998), and *Fiore v. Collagen Corp.*, 930 P.2d 477 (Ariz. Ct. App. 1996), *cert. denied,* 118 S. Ct. 684 (1998), and is also essentially the same as or closely related to those presented in *Kernats v. Smiths Industries Medical Systems, Inc.,* 669 N.E.2d 1300 (Ill. App. 1996), *cert. denied,* 118 S. Ct. 684 (1998), *Martin v. Telectronics Pacing Systems, Inc.,* 105 F.3d 1090 (6th Cir. 1997), *cert. denied,* 118 S. Ct. 850 (1998), and *Eddy v. Polymer Technology Corp.,* 692 A.2d 566 (Pa. 1997), *cert. denied,* 118 S. Ct. 850 (1998). Petitioner offers no better or different reasons for granting the petition here than were offered in those other cases. The Court denied the petitions in those cases and should deny this petition as well.

2. There is no conflict warranting review. The court below, in a carefully reasoned opinion, held that the federal requirements imposed on the manufacturer of a medical device in connection with the FDA's PMA process give rise to federal preemption under 21 U.S.C. § 360k(a). In so holding, the court conscientiously followed this Court's teachings in *Medtronic* and, as petitioner concedes, "[o]ther appellate courts have come to the same conclusion." Pet. 15. Indeed, after *Medtronic* no federal court of appeals or state supreme court has held to the contrary.

The cases upon which petitioner relies in asserting a conflict, *see* Pet. 13-16, either were decided by trial courts or state intermediate appellate courts or, like *Oja v. Howmedica, Inc.*, 111 F.3d 782 (10th Cir. 1997), and *Niehoff v. Surgidev*, 950 S.W.2d 816 (Ky. 1997), did not involve medical devices subject to the rigorous requirements imposed by the PMA process. Petitioner has not pointed to a single post-*Medtronic* decision by any federal appellate or state supreme court that is in direct conflict with the decision below.

Indeed, the federal appellate and state supreme courts that actually have considered the question presented here have uniformly concluded that "the PMA process, as opposed to the 'substantially equivalent' process at issue in *Medtronic*, can constitute the sort of specific federal regulation of a product that can have preemptive effect." *Mitchell*, 126 F.3d at 912. *See also Green v. Dolsky*, 685 A.2d 110 (Pa. 1996), *cert. denied*, 117 S.Ct. 1432 (1997); *Fry v. Allergan Medical Optics*, 695 A.2d 511 (R.I.), *cert. denied*, 118 S.Ct. 374 (1997). The Sixth Circuit in *Martin* and the Ninth Circuit in *Papike v. Tambrands, Inc.*, 107 F.3d 737 (9th Cir.), *cert. denied*, 118 S.Ct. 166 (1997), similarly have found preemption in closely related circumstances. In view of this decisional uniformity, there is neither need nor occasion for the Court to revisit the issues so recently considered in *Medtronic*.

3. As this Court recognized in *Medtronic*, whether section 360k(a) preempts state common law depends importantly on the context. A majority of the Court agreed that state common law duties may constitute requirements subject to preemption under the statute. *See* 116 S.Ct. at 2259-60 (Breyer, J., concurring), 2262-64 (O'Connor, J., concurring in part and dissenting in part). The Court held that the general state common-law requirements invoked by the plaintiffs there were not preempted, "but only after concluding that the federal labeling and manufacturing requirements at issue were not specific to [the medical device in question]." *Papike*, 107 F.3d at 742.

The broad federal requirements at issue in *Medtronic* "reflect[ed] important but entirely generic concerns about device regulation generally, not the sort of concerns regarding a specific device or field of device regulation which the statute or regulations were designed to protect from potentially contradictory state requirements." 116 S.Ct. at 2258. Consequently, the plaintiffs' common-law causes of action in that case did not interfere with the federal regulatory scheme and posed no "threat to federal requirements." *Id.* The Court took care to note, however, that in other contexts "'general' state requirements [may be] pre-empted." *Id.* at 2257. This is precisely such a case. As the Texas Supreme Court noted, petitioner's cause of action runs directly counter to the congressional purposes and objectives of the MDA. Pet. App. 38a.

4. The decision below plainly is not, as petitioner argues, "at odds with *Medtronic*." Pet. 16. This Court in *Medtronic* carefully distinguished between the abbreviated notification process at issue in that case and "the rigorous PMA review" satisfied by Zyderm in this case. 116 S.Ct. at 2247. In *Medtronic* "the agency simply allowed the pacemaker, as a device substantially equivalent to one that existed before 1976, to be marketed without running the gauntlet of the PMA process." *Id.* at 2254. Here, Zyderm successfully ran that gauntlet and was found to be safe and effective when manufactured and marketed in

accordance with specifications approved by the FDA. 46 Fed. Reg. 46394 (1981).

Although petitioner attempts to obscure the nature of the PMA process and to trivialize the requirements it imposes, that process of determining and assuring safety and effectiveness lies at the very heart of the regulatory program envisioned by Congress when it enacted the MDA. The stated purpose of the MDA is "to provide for the safety and effectiveness of medical devices intended for human use." *Medtronic*, 116 S.Ct. at 2245, quoting 90 Stat. 539. The PMA process is the regulatory mechanism by which this purpose is achieved. *Id.* at 2246-47. In turn, a central function of the MDA preemption statute is to insulate that process from state interference: section 360k(a) by its plain terms bars the states from interposing requirements conflicting with or departing from the federal requirements relating to safety and effectiveness imposed pursuant to the PMA process.

5. "During the PMA process, the federal government, it can truly be said, has 'weighed the competing interests relevant to the particular requirement in question, reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case . . ., and implemented that conclusion via a specific mandate on [the] manufacturer[].'" *Mitchell*, 136 F.3d at 911. This observation was confirmed, in this case, by "the specificity of the FDA's conditions in granting approval" to Zyderm. Pet. App. 36a.

Petitioner argues, in effect, that such specific federal requirements simply don't count under the MDA preemption statute "because the device's specifications originate with the manufacturer." Pet. 16. That is a nonsequitur. The origin of a federal rule or requirement is irrelevant. A federal agency may, for example, solicit rule proposals from trade groups or individuals. But once the agency adopts a proposal, it becomes the federal standard regardless of origin. That is the case here.

In most (although not all) instances, manufacturing, labeling, and other specifications do indeed originate with the manufacturer. But once the FDA approves those specifications, which it does only after intensive scrutiny, they become specific and binding federal requirements. The PMA approval order typically specifies, and did so in this case, that the manufacturer is required to adhere to the design, components, manufacturing methods, and labeling approved by the FDA in the course of the PMA process. See Pet. App. 6a-7a. Such requirements "are entitled to preemptive effect under the MDA as construed and applied in *Medtronic*." *Id.* at 37a.

6. Petitioner's discussion of her Texas DTPA claims, Pet. 18-20, appears to take issue with the Texas Supreme Court's analysis and characterization of those claims as a matter of state law. The court determined that her claim under the DTPA, in essence, is "that Zyderm was not safe" and that, to prevail, she "must prove that Zyderm as approved by the FDA is not safe." Pet. App. 37a, 38a. That determination, of course, is not subject to review here.

Petitioner's state law claim that Zyderm is not safe "contradicts not only the FDA's specific finding to the contrary but also the manufacturing, distribution, and labeling protocols approved by the FDA." Pet. App. 38a. It therefore is barred by the MDA preemption statute. This is plain common sense. Congress did not intend the FDA's findings of safety and effectiveness to be overridden by state court juries. That is a core principle of MDA preemption. It follows that a firm like Collagen is not subject to state law claims that its product is unsafe when, as here, it has strictly adhered to specific federal requirements in the manufacture and distribution of a medical device that the FDA itself has found to be safe and effective.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted,

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